REMARKS

Applicant respectfully requests reconsideration. Claims 40-44 and 54-56 were previously pending in this application. No claims are amended or canceled herein. Claims 40-44 and 54-56 are still pending for examination with claims 40 and 54 being independent claims. No new matter has been added.

Double Patenting

Claims 40-44 and 54-56 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 23 of U.S. Patent No. 7,935,675 (the '675 patent) in view of Krieg et al (7723500, the '500 patent). Applicant disagrees.

Claims 40-44 and 54-56 are not obvious based on double patenting over claims 1 and 23 of the '675 patent in view of the '500 patent because the '500 patent is not prior art against the instant patent application. Although it is appropriate to present prior art to demonstrate that a claimed invention is obvious over the claims of a co-owned patent, the prior art must be prior art under 35 USC 102. The '500 patent has an earliest priority date of July 15, 1994, which is the same date as the earliest priority date of the instant patent application. Therefore, the '500 patent is not prior art against the claims of the instant patent application. On this basis alone, the rejection should be withdrawn.

Additionally, claims 40-44 and 54-56 are not obvious based on double patenting over claims 1 and 23 of the '675 patent because the claimed invention is not simply an obvious variant of the claims of the '675 patent. In concluding that the rejection for obviousness type double patenting is proper, the Examiner indicated that there is overlap between the claimed method and the claims of the issued patent. The fact that the instant claims and the '675 patent have "overlapping subject matter" is not determinative in an obviousness type double patenting rejection. Applicant's respectfully submit that the claimed subject matter must be obvious in view of the cited claims to support an obviousness type double patenting rejection.

The claims in the issued patent are distinct from the claims in the present application and in some instances, overlap with, and in other instances, do not overlap the instant claims. In the instant application the claimed invention is directed to a method for stimulating an immune response to a vaccine by administering a CpG immunostimulatory oligonucleotide, a vaccine and a delivery complex to the subject. The claims of the '675 patent are directed to methods of treating asthma by administering an oligonucleotide and a delivery complex, but are silent with respect to the administration of a vaccine.

The appropriate legal analysis for obviousness type double patenting requires a determination that the differences between the claimed inventions would have been obvious to one of ordinary skill in the art. The court in General Foods Corp. v. Studiengesellschaft Kohle GmbH has stated that "the determining factor in deciding whether or not, there is double patenting is the existence vel non of patentable differences between two sets of claims." "It is important to bear in mind that comparison can be made only with what invention is claimed in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim defines and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference." Mere overlap is not enough.

The court in General Foods makes it clear that whether a claim overlaps with a pending claim, is not the appropriate test for double patenting. The fact that there may be overlap between the claims does not establish that the pending claims are obvious variants of the claims of the issued patents.

The court in In re Vogel set forth a two part test for determining the appropriateness of a double patenting rejection. "The first question is: Is the same invention being claimed twice?" If the answer to the first question is no, "the second analysis question is: Does any claim in the application define merely an obvious variation of an invention disclosed and claimed" Id. at 441, 164 USPQ at 622.

The record is clear that the same invention is not being claimed twice because the two sets of claims are not directed to identical subject matter. The pending application claims a method of producing an immune response to a vaccine and a CpG oligonucleotide ionically associated with a delivery complex. The issued patent claims a method of treating asthma by administering a CpG oligonucleotide and a delivery complex. The claims do not recite the administration of a vaccine. Thus, the claims of the issued patent are not the same as the claims of the pending application.

Further, the claims in the instant application do not define merely an obvious variation of an invention disclosed and claimed in the issued patent. The pending claims recite substantial and nonobvious limitations when considered in view of the issued claims. Significantly, a method for producing an immune response to a vaccine involves the production of an antigen specific immune response. The fact that a composition of an oligonucleotide in the absence of a vaccine or antigen (the issued claims of the '675 patent are silent) can be used to treat asthma is not sufficient to provide a reason able expectation that such a composition would produce an antigen specific immune response.

Even in the absence of the above-arguments, the rejection based on obviousness-type double patenting is improper because the claims are being rejected on the basis that the claims of the '675 patent encompass the instantly claimed subject matter and that such subject matter is included in the specification. For instance the Examiner points to the speciation of the '675 patent for support for the limitations that the CpG oligonucleotide has greater than two CpG dinucleotides and that the delivery complex is ionically linked to the oligonucleotide. It is clear in the case law that the proper test of whether obviousness type double patenting is appropriate is whether the instant claims were obvious over the claims of the issued patent, not over the teachings of the specification. The instant claims are neither the same as nor an obvious variant of the invention claimed in the issued patent.

The disclosures regarding 1. greater than 2 CpG dinucleotides and 2. the ionic linkage in the specification of the issued patent is being improperly read into the claims in order to make the double patenting rejection. This is not appropriate. Though the specification can be used as a dictionary to interpret the scope of the claims, the limitations regarding greater than 2 CpG

dinucleotides and the ionic linkage cannot be read into the issued claims. The broadest possible interpretation without reading specific disclosure from the application into the claims, of the issued claims is the use of a genus of CpG oligonucleotides not limited by the requirement of having greater than 2 CpG dinucleotides and being formulated with a carrier but not limited to being ionically linked to the carrier for treating asthma. The instant claims include the limitations that the CpG oligonucleotide has greater than two CpG dinucleotides and that the delivery complex is ionically linked to the oligonucleotide and that such a composition is used to stimulate an immune response to a vaccine. Therefore it is requested that the rejection be withdrawn.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communications does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70083US05.

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Respectfully submitted,

By _____

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